

Fletcher, Rachel

From: Herrick, Jacquelyn
Sent: Wednesday, September 15, 2021 2:15 PM
To: Hart, Ellen; Hugunin, Kelly; Clarke, Angela
Cc: Suarez, Mark; Waterworth, Rebecca; Hawkins, Caleb; Kaul, Monisha; Johnson, Marion; Mallampalli, Nikhil; Dutch, Veronica; Jennings, Susan; Echeverria, Marietta; Matuszko, Jan; Vogel, Dana; Aubee, Catherine; Reaves, Elissa; Colby, Deanna; Di Salvo, Paul; Shuler, Jamey; Britton, Cathryn; Biscoe, Melanie; Fletcher, Rachel; Miller, David; Niman, Aaron; Recore, Shanna; Rossmeisl, Colleen; Breeden-Alemi, Julie; Backus, Byron; Andrews, Elizabeth; Saunders, Jennifer; Leifer, Kerry; Hospital, Jocelyn; Walls, Cassi; Spatz, Dana; VanAlstine, Julie
Subject: RE: Welcoming FDA - Seresto Review
Attachments: Slides for FDA.pptx

FDA Colleagues,

We look forward to speaking with you tomorrow regarding the Seresto review.

In advance of the meeting, we thought it would be helpful to share some general background on our Incident Data System and enhanced incident data for Seresto and other Elanco products. We will probably not have time to cover the slides in extensive detail during the meeting, but the slides relate to agenda items 3(b), 3(c), 4, and 5 and will hopefully help set the stage for future technical meetings.

Please let us know if you have any questions or comments in advance of the meeting.

Many thanks,
Jackie

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-----Original Appointment-----

From: Herrick, Jacquelyn
Sent: Wednesday, September 01, 2021 9:43 AM
To: Herrick, Jacquelyn; Shuler, Jamey; Britton, Cathryn; Biscoe, Melanie; Fletcher, Rachel; Miller, David; Niman, Aaron; Recore, Shanna; Rossmeisl, Colleen; Breeden-Alemi, Julie; Backus, Byron; Andrews, Elizabeth; Saunders, Jennifer; Leifer, Kerry; Hospital, Jocelyn; Walls, Cassi; Spatz, Dana; VanAlstine, Julie; Hart, Ellen; Hugunin, Kelly; Clarke, Angela; Echeverria, Marietta; Matuszko, Jan; Vogel, Dana; Aubee, Catherine; Reaves, Elissa; Colby, Deanna; Di Salvo, Paul
Cc: Suarez, Mark; Waterworth, Rebecca; Hawkins, Caleb; Kaul, Monisha; Johnson, Marion; Mallampalli, Nikhil; Dutch, Veronica; Jennings, Susan
Subject: Welcoming FDA - Seresto Review
When: Thursday, September 16, 2021 1:00 PM-2:00 PM (UTC-05:00) Eastern Time (US & Canada).
Where: Microsoft Teams Meeting

9/9 Update: Add the agenda and attach the enhanced 6a2 letter EPA sent to Elanco.

AGENDA:

Meeting Goal: Introduce FDA to EPA review of Seresto, discuss FDA's role and begin to organize the collaborative review.

- 1) Welcome and introductions, including individual areas of expertise (*Jamey, Jackie, Colleen*)
 - 2) Background on Seresto (*Jackie*)
 - a. Brief history
 - b. Incidents & 2021 news articles
 - c. CBD Petition (*Rachel*)
 - 3) Purpose of the review/Scope (*Jackie*)
 - a. Goal of the review
 - b. Data that were requested (6a2 letter)
 - c. Overview of data that were submitted by Elanco (*Colleen/Aaron*)
 - 4) Recent analyses and current status of EPA review (*Colleen/Aaron/James*)
 - 5) General overall approach moving forward (*Colleen*)
 - a. FDA's anticipated role – discussion (*all - FDA/EPA*)
 - 6) Next steps (*Colleen, Jackie*)
 - a. Recurring meetings with technical team
 - b. Recurring full team meetings
-

Hi all,

This will be our first meeting with our FDA colleagues. I hope we can welcome (& thank) them, give an overview of the review, and start discussion on what specific areas of the review we most need their help.

BEAD, we'll keep you looped in, but feel free to skip for now!

Let me know if you have any questions ahead of this meeting.

Jackie

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